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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,543	11/12/2003	Linda S. Powers	13368.0001 (DIV. III)	6900
7590 10/05/2005			EXAMINER	
K. S. Cornaby Suite 1500 170 South Main Street Salt Lake City, UT 84101-1644			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/706,543	Applicant(s) POWERS ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Currently, claim 1 is pending and under consideration. In the prior action, mailed on December 16, 2004, claims 1-3 were pending and rejection. In the Response of May 9, 2005, the Applicant cancelled claims 2 and 3, and amended claim 1.
2. Because this action raises new grounds of rejection not necessitated by amendment, the action is made Non-Final.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 12, 2005, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.
4. It is noted that U.S. patents 6,780,602 and 6,124,102 were lined through, and not initialed, in the IDS. This is because these references were previously considered and made of record in the prior action.

Specification

5. **(Prior Objection- Withdrawn)** The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In view of the amendment of the specification, the objection is withdrawn.

Claim Objections

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6. **(Prior Objection- Withdrawn)** Claim 1 was objected to because of the following informalities: a comma should be inserted between the terms “discharge” and “and” in line 6 of the claim. In view of the amendment of the claim, the objection is withdrawn.

7. **(New Objection- Necessitated by Amendment)** Claim 1 is objected to because of the following informalities:

The subparts of claim 1 vary in their presentation in that part (a) begins with a lower case letter, while parts ((b)-(d) begin with capital letters. To maintain uniformity, each subpart of the claim should be presented in a similar manner (i.e. all parts should begin with either a capital or with a lower case letter).

In subpart, (a), the claim indicates that a microbial cell is ruptured through exposure to conditions selected from an indicated group. Among the conditions identified are “holins.” However, holins are a type of compound, not a condition. It is suggested the claim be amended to indicate that the method is “treatment with holins” or “holing treatment” to maintain consistency with the language of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(Prior Rejection- Withdrawn)** Claims 1-3 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what solution was being referred to in the

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phrase “exposing the solution containing microorganisms to conditions resulting in the rupture of the microorganisms.” In view of the amendment of claim 1, and the cancellation of claims 2 and 3, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 1-3 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was unclear if the “protein analyte” of step (b), and the “analyte” of steps (c) and (d) are the same as the protein identified in the claim preamble. In view of the amendments to the claim, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims, the rejection is withdrawn.

12. **(New Rejection)** Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on a method including a step for rupturing a microorganism wherein said rupturing to be conducted according to one of a group of methods. However, the claim introduces the group as “comprising” one of the identified groups. It is therefore not clear what the scope of the claim is. I.e., it is not clear if the claim is limited to the indicated methods or if other methods may be used. The claim is therefore rejected as not following proper Markush type claim language. See, MPEP 2173.05 (h). Clarification is required.

It is suggested that the claim be amended such that the mode of rupturing is selected from the group - - consisting of - , rather than from the group “comprising” the indicated modes.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. **(Prior Rejection- Withdrawn)** Claims 1-3 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking written description support for embodiments that allow for the rupture of the microorganisms through plasma discharge. In view of the cancellation of this subject matter from the claims, the rejection is withdrawn.

15. **(New Rejection)** Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. his claim is drawn to methods for the identification of a protein analyte comprising the use of a tethered ligand, wherein the tether is at least forty in length. However, while the present application discloses the use of tethers with a length of at least 40 , the application discloses such tethers only for the use of ligands to whole microbial cells. Page 10.

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With respect to the ligands to peptides as used in the presently claimed method, the application discloses peptides of at least 6 , but not the genus of tethers limited to those of at least 40 in length. See also, originally filed claim 1 (wherein the method of detecting a protein comprises the use of a linker of at least 6 . The claims are therefore rejected as reading on new matter to the application.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. **(Prior Rejection- Maintained)** Claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al. (WO 98/49557) and further in view of the teachings of Waskiewicz et al. (EP 0 286 434) and Trudil (U.S. 6,395,504). Claims 2 and 3 have been cancelled. Claim 1 has been amended to include a step of including a washing step in the removal of the target analyte from the solution in which it is identified. The rejection is restated as a rejection of claim 1 over the teachings of Powers in view of Fodor (U.S. 6,124,102- of record and cited in the rejection in the prior action), further in view of Waskiewicz and Trudil.

The Applicant traverses the rejection on three general grounds. First, the Applicant notes asserted deficiencies in the teachings of Powers as the primary reference. Second, the Applicant asserts that the teachings of Fodor fail to render obvious the linker lengths of the present application. Second, the Applicant argues that the teachings of Waskiewicz and Trudil fail to

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render obvious the detection of microorganisms via the detection of cytosolic proteins. These arguments are not found persuasive.

The Applicant's first argument in traversal is that the teachings of Powers are deficient as a primary reference in that the reference fails to teach three elements of the claimed method. The three elements that the Applicant asserts are not disclosed by Powers are 1) a step of washing in the removal of the bound analyte from the solution, 2) the use of photostable linkers, and 3) the indicated tether lengths.

With respect to the argument that Powers does not teach a washing step in the disclosed methods it is noted that the reference does not, as Applicant asserts, specifically teach a washing step before the detection of the bound analyte. However, the reference is teaching a binding assay. It is well known in the art for those in the art conducting a binding assay to include a washing step for the removal on non-bound analytes. See e.g., Fodor, columns 16-17. See also, U.S. 5,935,804, columns 33-34; U.S. 5,817,461, column 37; and U.S. 4,271,140, column 9 (each disclosing binding assays in which unbound materials are washed from the target analyte and ligand conjugates). Further, because the Powers method relies on the ability to detect the fluorescence of bound analyte, it would have been apparent to those in the art that unbound interfering materials would have to be removed prior to the detection step. Thus, based on the knowledge in the art, and the requirements of the method disclosed by Powers, it would have been obvious to those skilled in the art to include a washing step in the binding assay disclosed by Powers. The Applicant's assertion that Powers does not teach such a step in therefore not found persuasive in avoiding the obviousness rejection.

With respect to the assertion that the Powers reference does not teach the use of photostable linkers, two items are noted. First, while the reference does not teach the photostable property of the linkers, the reference does disclose the identical linkers disclosed in the present application for use in methods of detecting analytes by fluorescence polarization- which would require photostability. Thus, the photostable property asserted by the Applicant would be inherent to the linkers disclosed and used by Powers. Further, it is also noted that the Applicant's present assertion that the linkers of Powers are not photostable is inconsistent with a statement of inherency similar to that forwarded by the Examiner above. In particular, the Applicant specifically states that photostability is inherent to the linkers disclosed in the Powers reference in the Applicant's interview summary filed May 17, 2005 in copending application 10/706,547 (published as U.S. 2004/0096910, prosecution documents of which are available on Public PAIR). This assertion is therefore not found persuasive.

With respect to the lengths of the tethers, it was admitted in the prior action that the Powers reference does not teach the claimed tether length. However, it was also asserted that, assuming that the claimed tether lengths were optimal for the detection of peptides in a solution, the additional teachings of the Fodor reference would have rendered such obvious.

The second argument in traversal is an assertion that the teachings of the Fodor reference fail to render obvious the linker lengths disclosed by the present application. Applicant states that the assay disclosed by the Fodor reference is different from the assay of the present application, and that because of this, the optimum lengths of linkers for the method in Fodor would be different from the optimum lengths for the presently claimed method. This argument is not found

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persuasive. Fodor is cited only as indicating that it was known in the art that the lengths of linkers used to attach a ligand to a substrate is to be optimized for the binding of the target “receptor.” I.e., the reference teaches that it would have been obvious to one of ordinary skill in the art to optimize the length of a linker between a ligand and a substrate for binding to a target analyte of interest. As such, it would have been obvious to those in the art to optimize the length of the linker in the Powers reference for the detection of that target peptides for the ligand used. The more specific teachings of Fodor with respect to the other methods disclosed therein provide no teachings leading away from this conclusion. The argument that the teachings of Fodor do not render the claimed tether lengths obvious is therefore not found persuasive.

The Applicant’s third argument in traversal is that the teachings of Waskiewicz and Trudil fail to render obvious the detection of microorganisms via the detection of proteins contained inside of the microbe. As indicated by the Applicant, these references are directed to the detection of microorganisms by the detection of enzymatic activity upon the lysis of the microbial cells, and do not teach methods for the detection of a specific protein. Nonetheless, each of these references teach that those in the art were aware that a microbe could be identified by detection of proteins or other constituents released upon lysis of the microbial cells. From these teachings, and the teachings of Powers indicating that microbial proteins may be detected by the methods disclosed therein, it would have been obvious to those of ordinary skill in the art that the methods of Powers could be used for the detection of the intracellular microbial proteins upon lysis of the microbial cells. Thus, while the teachings of either Waskiewicz or Trudil are, alone, insufficient to teach the claimed method, the combination of these references with the

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teachings of Powers are sufficient to render the method obvious. The Applicant's arguments regarding the insufficiency of the Waskiewicz and Trudil references are therefore not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. **(Prior Rejection- Maintained)** Claims 1-3 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 21, 23, and 30 of U.S. Patent No. 6,780,602 in view of Trudil, and Waskiewicz as described above. The Applicant argues that the current amendment avoids the obviousness type rejection. However, it is noted that none of the cited claims of the patent are drafted to exclude the identification of cytosolic proteins. It is therefore not clear how the amendments of the present application avoid the double patenting rejection. The rejection is therefore maintained.

20. **(Prior Rejection- Maintained)** Claims 1-3 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 21-23, and 26 of copending Application No. 10/706,547 or over claims 38, 39, 41, and 47 (renumbered as claims 1, 2, 4, and 10 respectively) of copending Application NO. 10/706,542 in view of Powers, Trudil, and Waskiewicz as described above.

The Applicant argues that the amendment of claim 1 of the present application avoids the double patenting rejections in that they define an invention other than those claimed in the copending applications. This argument is not found persuasive with respect to the 10/706,547 application because the claims of that application are drawn to the detection of any biological analyte, or to a proteinaceous toxin. The claims of the copending application do not require that these analytes or toxins be expressed only on the cell surfaces of microorganisms. Thus, the claims of the copending application are therefore either generic to, or claim obvious overlapping subject matter with, the current application as described in the prior action.

With respect to the 10/706542 application, it is noted that a restriction requirement has been made in that case, and an election for the use of ligands specific to outer membrane proteins was made. However, none of the claims over which this double patenting rejection were made are limited to such embodiments, and remain generic to, or overlapping with, the presently claimed inventions as described in the prior action.

Because the claims of the copending applications read on currently claimed subject matter, and because the present application claims an obvious variation of the methods claimed in those applications, the amendment of claim 1 in the present application does not overcome this rejection. For these reasons, and for the reasons of record, the provisional rejection is maintained.

Conclusion

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21. No claims are allowed.
22. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

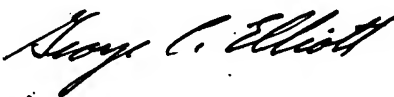
Sanders, U.S. 5,888,725; Hodgson et al., U.S. 5,801,234; Nauta et al., U.S. 6,124,525. The teachings of these references render obvious the use of bacteriophages, holins, chemical or physical treatment, and freeze-thaw cycling for the rupture of microbial cells such that the contents are spilled into a solution. See e.g., Sanders, column 2 lines 20-31; Nauta, column 6 lines 43-49; and Hodgson, column 9 lines 41-45. These references are considered redundant to the Trudil and Waskiewicz references (which teach the rupture of microbial cells using lytic enzymes and detergents [i.e. chemical treatment]) with reference to the mode of releasing intracellular proteins from the cells.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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